AUG - 3 2007

VIII. 510(k) Summary of Safety and Effectiveness

Arthrex Biocomposite Interference Screw

Manufacturer / Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, Florida 34108-1945
510(K) Contact	Ann Waterhouse, RAC Regulatory Affairs Project Manager Telephone: (239) 643-5553 ext. 1179 FAX: (239) 598-5539
Trade Name	Interference Screw
Common Name	Fastener; Screw, Fixation, Bone
Product Code/Classification Name	HWC/ 21 CFR 888.3040 Fastener, Fixation, Nondegradable, Soft Tissue Smooth or threaded metallic bone fixation fastener MAI/ 21 CFR 888.3030 Fastener, Fixation, Biodegradable, Soft Tissue
Predicate Devices	Interference Screw Family : K062466 DePuy Mitek, K060830 Mitek Worldwide, K032717 Smith & Nephew, K051310 Smith & Nephew, K002274
Date Prepared:	May 31, 2007

Device Description and Intended Use

The Arthrex Biocomposite Interference Screws are intended to be used for fixation of tissue including ligament or tendon to bone and bone tendon bone. Interference fixation is appropriate for surgeries of the knee, shoulder, elbow, ankle, foot, and hand/wrist where the sizes offered are patient appropriate. Specifically;

Shoulder. Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

Foot/Ankle: Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Hallux Valgus Reconstruction, Midfoot Reconstruction, Metatarsal Ligament Repair, Flexor Hallucis Longus for Achilles Tendon reconstruction, tendon transfers in the foot and ankle

Knee: Anterior Cruciate Ligament Repair, Posterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Illiotibial Band Tenodesis

Elbow: Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction

Hand/Wrist: Scapholunate Ligament Reconstruction, Ulnar Collateral Ligament Reconstruction, Radial Collateral Ligament Reconstruction, Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty), Carpal Ligament Reconstructions and repairs, tendon transfer in the hand/ wrist

Substantial Equivalence Summary

The Arthrex Biocomposite Interference Screw is substantially equivalent to the predicate devices listed above in which the basic features and intended uses are the same. Any differences between the Biocomposite Interference Screw Family and the predicate devices are considered minor and do not raise questions concerning safety and effectiveness. Based on the information submitted, Arthrex, Inc. has determined that the new Biocomposite Interference Screw is substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 2007

Arthrex, Inc.
% Ann Waterhouse, RAC
Regulatory Affairs Project Manager
1370 Creekside Boulevard
Naples, Florida 34108-1945

Re: K071176
Trade/Device Name: Biocomposite Interference Screw
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI, HWC
Dated: July 23, 2007
Received: July 24, 2007

Dear Ms. Waterhouse:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

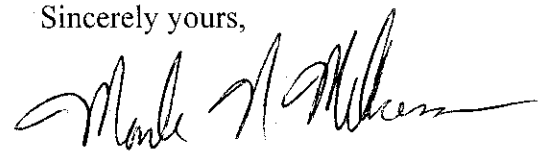
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

III. Indications for Use Form

510(k) Number (if known): K071176 **510(k) Number** K071176

Device Name: Arthrex Biocomposite Interference Screw

Indications for Use:

The Arthrex Biocomposite Interference Screws are intended to be used for fixation of tissue, including ligament or tendon to bone, or a bone/tendon to bone. Interference fixation is appropriate for surgeries of the knee, shoulder, elbow, ankle, foot, and hand/wrist where the sizes offered are patient appropriate. Specifically;

Shoulder: Rotator Cuff Repairs, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction

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Knee: Anterior Cruciate Ligament Repair, Posterior Cruciate Ligament Repair, Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Illiotibial Band Tenodesis

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Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)